

Dear Ms. Mrema,

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In line with the outcomes of the first part of the third meeting of the Open-ended Working Group on the Post-2020 Global Biodiversity Framework, the Wellcome Sanger Institute is pleased to submit its views on how to address digital sequence information on genetic resources under the Convention on Biological Diversity and the Nagoya Protocol.

Introduction

1. The Wellcome Sanger Institute, based on the Wellcome Genome Campus, Hinxton, UK, is a world-leading hub for genomes and biodata research. The campus is also home to EMBL-EBI, Connecting Science, Sanger Institute spin-out companies, start-up companies and Genomics England.
2. The Wellcome Sanger Institute uses information from genome sequences to advance understanding of biology and improve health. We use science at scale to tackle the most challenging global health research questions.
3. The Wellcome Sanger Institute is wholly committed to open access science: we share our data, publications, materials and resources to enable global research and to accelerate translation.
4. Digital sequence information on genetic resources (DSI) holds tremendous value for understanding biology and evolution. The success of genomics is a direct result of DSI being freely available and shared globally in easy-to-access public databases. This widespread sharing of DSI is fundamental for advancing research and driving innovation, for example, by addressing conservation challenges, delivering actionable public health strategies and responding rapidly to global public health emergencies.
5. Here, we present two overarching principles that we believe must be considered before adopting policy approaches, options or modalities for addressing DSI under the Convention on Biological Diversity and the Nagoya Protocol, followed by an assessment of the policy options outlined in Annex II of document CBD/WG2020/3/4 "Digital sequence information on genetic resources".

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Principle 1 – Open access to DSI drives scientific research and supports equitable benefit sharing

6. We define open access as having no barriers to access, including financial, legal and technical barriers.
7. The Wellcome Sanger Institute shares DSI free of charge, but access to the majority of our human DSI requires a data access agreement because of the sensitivities around human genomic data. Anecdotally, we know that the requirement to sign a data access agreement can be a barrier to access, particularly for researchers in low and middle income countries.
8. Open and unrestricted sharing of DSI drives research and innovation by improving scientific reproducibility and integrity, circumventing the substantial costs of reproducing DSI, and playing a crucial role in solving complex global challenges through the facilitation of collaborations between scientists around the world. To impose terms and conditions or access agreements would seriously undermine the value, accessibility and sustainability of DSI.
9. Public health emergencies require rapid responses. The rapid and unconstrained availability of DSI from genetic resources is critical for quickly determining how the causative pathogen infects hosts, how the disease is transmitted and how the pathogen is evolving. This information is vital for informing emergency response tactics and public health strategies. This process is time-sensitive and delays due to the establishment and negotiation of licencing agreements on a bilateral basis could be disastrous for public health.
10. Open access is necessary to achieve the United Nations Sustainable Development Goals, as restrictions on sharing of DSI would hamper research on, for example, human health, climate change, and food security. In addition, such restrictions would hinder research into biodiversity, thus potentially undermining the conservation of biological diversity, the first objective of the CBD.
11. Most DSI usage does not lead to commercialisation and generation of profit, therefore only limited direct monetary benefits might be shared from DSI use. In contrast, the open access to DSI in public databases constitutes a major benefit to everyone globally, including researchers from LMICs. Restricting access would likely disproportionately affect researchers from LMICs and thus worsen inequities in the receipt of benefits arising from the use of genetic resources in research.

12. Therefore, to avoid significant negative impacts on research and development, biodiversity and benefit sharing, any policy approach that addresses DSI must ensure that DSI remains openly available and with no restrictions to access.

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Principle 2 – A simple, multilateral system could ensure benefits that arise from the use of DSI are shared equitably whilst preserving open access

13. A bilateral system fails to acknowledge that, unlike physical genetic resources, the value of DSI comes from aggregated datasets where patterns of conserved features or differences are identified through comparison with thousands of other sequences. As such, a bilateral system would significantly hinder the comparison of global sequences, prevent basic bioinformatics analyses and put immense pressure on research support services. A multilateral approach would be a far more appropriate way to address how DSI is used.

14. Furthermore, a bilateral system would not be a suitable way to address the current DSI landscape. Such a system would rely on the tracing of each DSI use back to the source, but the huge volume of DSI in publically-accessible databases would make this challenging and costly. Currently, only 16% of nucleotide sequence data entries in the International Nucleotide Sequence Database Collaboration (INSDC) are currently country-tagged¹, presenting a near insurmountable barrier to implementation of a bilateral system.

15. A bilateral system allows for divergence in benefit sharing requirements depending on the DSI's country of origin. This could place some countries at a disadvantage as users go 'jurisdiction shopping', where they choose to access DSI from countries that stipulate no or fewer benefit-sharing requirements.

16. The majority of DSI in the INSDC has been geographically sourced from the global north, thus under a direct bilateral arrangement, benefits arising from the use of DSI would in theory be distributed largely to the global north. It should be noted that large collaborative sequencing projects such as the Darwin Tree of Life (DToL) project, which seeks to sequence all eukaryotic species within the British Isles (approx. 66,000 species) will input a huge amount of DSI into the INSDC that could then (unintentionally) benefit the UK financially. The motivation behind large collaborative projects like DToL is to advance biology, conservation and biotechnology globally, not to generate monetary benefit for the UK.

17. A multilateral solution that decouples the use of DSI from the sharing of benefits with the specific provider country could circumvent many of the issues arising from a bilateral system. A multilateral system could preserve open access and make the benefit sharing process simpler and future-proof by removing the need to trace each DSI to its country of origin. In addition, a multilateral system

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¹ Rohden, F, Scholz, AH. The international political process around Digital Sequence Information under the Convention on Biological Diversity and the 2018–2020 intersessional period. *Plants, People, Planet*. 2021; 00: 1– 10. <https://doi.org/10.1002/ppp3.10198>

would mitigate jurisdiction shopping while acknowledging that the true value of DSI comes from aggregate datasets.

18. Importantly, a centralised, multilateral system could ensure that benefits that arise from the use of DSI are targeted to where they are most needed in a fair and equitable manner. Both non-monetary and monetary benefit-sharing approaches could be used to build capacity around the generation, use and analysis of DSI in LMICs, particularly with the aim of conserving biological diversity.

Assessment of the suggested policy options for addressing access and benefit-sharing of digital sequence information related to genetic resources

19. Below is an assessment of the policy options outlined in Annex II of document CBD/WG2020/3/4 "Digital sequence information on genetic resources".

a. Option 0: Status Quo

This policy option presents legal uncertainties and complications when navigating different legislation across countries.

b. Option 1: DSI fully integrated into the Convention on Biological Diversity and the Nagoya Protocol

DSI cannot be considered equivalent to a genetic resource given that the true value of DSI comes from aggregated datasets and not the sequence in isolation. This policy option would significantly hinder open access, be detrimental to research and innovation and cause negative downstream impacts on biodiversity and benefit sharing. Costly mechanisms would be required to trace DSI back to its source and there would be a significant risk of 'jurisdiction shopping'. It should be noted that given the majority of DSI in the INSDC has been geographically sourced from the global north, benefit-sharing could unintentionally and counterintuitively benefit the global north.

c. Option 2.1: Each country has a standard MAT/licence

Although a standardised MAT could enable swifter compliance, the inability to renegotiate MAT could hinder downstream researchers (both academic and commercial) from accessing DSI. Moreover, a bilateral approach poses significant challenges to open access, DSI traceability, administrative resource and jurisdiction shopping and does not acknowledge the inherent value of DSI in aggregated datasets.

d. Option 2.2: Standard MAT/licence at the international level

Although an internationally standardised MAT offers a more pragmatic solution than Option 2.1, we must not underestimate the complexity of harmonising terms across jurisdictions. As with Option 2.1, the inability to renegotiate MAT terms could hinder downstream researchers (both academic and commercial) from accessing DSI.

Furthermore, this option challenges open access and could place significant bureaucratic and resource burdens on research organisations.

e. Option 3.1: Payment for access to DSI

Fees to access DSI will hinder research and would likely disproportionately affect LMIC researchers, early career researchers and small and medium-sized enterprises.

Recognising the benefits of open science, most funding bodies and publishers now stipulate that research outputs, including DSI, are made freely and openly accessible – hence this policy option directly conflicts with a long-established campaign to drive open access in the research sector based on the position that genomic data is a public good.

Furthermore, requiring payments for access to individual DSI would be impractical, given the value of DSI comes from the comparison of many sequences. Any scenario requiring commercial companies to pay for access to DSI must be reasonably priced and determined in consultation with the commercial life sciences sector. If such a system is adopted, the maintenance of resources and development of new analysis tools should remain relevant and desirable for both academic and commercial researchers. Any incentive to attract fee-paying commercial companies to these resources should not undermine or de-prioritise the needs of the academic sector.

f. Option 3.2: Other payments and contributions

Charging a fee for a DSI-related service or levy on products or services associated with DSI could have the unintended consequence of increasing the cost of sequencing, making it less affordable and accessible, particularly to LMIC researchers. It must be noted that many of these products and services could be purchased with the intention of sequencing and/or researching genetic resources that are out-of-scope of the CBD (e.g. human DSI). Similarly, this could impact clinical sequencing, which could negatively impact public health and surveillance. A marketing programme where a label or badge can be used by companies committed to redirecting benefits to a multilateral fund could work well for some sectors where there is consumer choice e.g. the perfume industry. However, for many healthcare products (e.g. prescription medicines), such a badge would not be seen by the consumer and healthcare practitioners will choose based on patient health rather than biodiversity values.

g. Option 4: Enhanced technical and scientific cooperation

International collaborations are imperative to our ability to tackle complex global challenges and we frequently collaborate with researchers in provider countries. We support increasing capacity building efforts as part of a policy solution to address DSI. However, such efforts should be considered best practice rather than enforced.

Capacity-building efforts are not trivial – they can be contractually challenging, costly, and place significant time pressures on researchers who conduct the activities alongside their research. Indeed, capacity building efforts are more feasible for larger-scale

projects and less so for individual researchers and small research groups. It should be noted that, compared with monetary benefit sharing, the impact of technical and scientific capacity building can be difficult to measure, which could lead to disputes over what was contractually agreed and difficulties determining whether it has been conducted successfully and effectively.

h. Option 5: No Benefit Sharing from DSI

Countries should share equitably in the benefits arising from research and development which utilise sovereign genetic resources, but existing proposals regarding DSI have the potential to do more harm than good while failing to achieve the goals of the CBD.

In conclusion, a multilateral system that decouples the use of DSI from the sharing of benefits with the specific provider country recognises how DSI is used in practice, offers the potential to ensure open access, and allows for fair and equitable benefit sharing. The specific approach taken must ensure complete open access to DSI, i.e. no technical, financial or legal barriers to access for anyone, so that research and development can continue unhindered. Any restrictions to access would risk holding back research into public health and biodiversity and would disproportionately affect researchers from LMICs, thus undermining the objectives of the CBD.

Thank you for considering this submission. Please let me know if you would like more information or clarification on any of the points outlined above.

Kind regards,

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